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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/462,094

Applicant(s)
Pang et al.

Examiner
Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 3-6, 9-14, and 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7, 8, and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Examiner acknowledges preliminary amendment filed 10/18/01 adding claims 16-18. Claims pending are 1-18.

Response to restriction requirement is acknowledged. Applicant elected Group I, claims 1,2,7,8,15 drawn to a shark cartilage extract and pharmaceutical compositions of the same. The election is made with traverse in regard to restriction between Groups I, II, and VII. In regard to Group II, Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different processes such as methods of Groups III-VI. In regard to restrictions between Group I and Group VII, the claims drawn to the product of Group I are in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need to be established and not that of the recited process steps. As there are no structural characteristics distinguishing the claimed extract from shark cartilage extracts taught in prior art, it is assumed that said extract can be prepared by other methods known in the art (see art rejections below).

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Consequently, Groups I and VII are patentably distinct. The restriction requirement is still deemed proper and is therefore made FINAL.

In regard to new claims 16-18, claims 16, 17 and claim 18 belong to Groups II and VII, respectively. As such, the claims are withdrawn from consideration together with their respective groups.

Claims 3-6,9-13,14,16-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

Abstract

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Drawings

3. The drawings have been approved.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how cooling of a suspension (in two instances following extraction step) to 40-60°C may occur when the extraction as claimed (in the range from 4 to 100°C) may be carried out at temperatures lower than the cooling step.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

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later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[®] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1,7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Dupont et al (US Patent 5,618,925).

Instant claims 1,7 are drawn to shark cartilage extract and pharmaceutical composition comprising thereof.

Dupont et al teach shark cartilage extract. See summary and claim 1. The reference anticipates instantly claimed shark cartilage extract. There is no distinguishing characteristics claimed for the extract; therefore the claimed and referenced extracts are presumed to have same activities. As for the claimed anti-PTH activity of the extract, it has been held that where applicant claims a composition in terms of function, property or characteristic where said function is not explicitly shown by the reference and where the examiner has explained why the function, property or characteristic is considered inherent in the prior art, it is appropriate for the examiner to make a rejection under both the applicable section of 35 USC 102 and 35 USC 103 such that the burden is placed upon the applicant to provide clear evidence that the respective compositions do in fact differ. Since the Office does not have the facilities for examining and comparing applicants' extract with the extract disclosed in the prior art, the burden is on applicant to show novel or unobvious

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difference between the claimed product and the product of the prior art. See *In re* Best, 562 F.d. 1252, 195 USPQ 430 (CCPA 1977) and *In re* Fitzgerald et al., 205 USPQ 594.

6. Claims 2,15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Dupont et al (US Patent 5,618,925).

Claims 2,15 are in product-by-process format and is are drawn to a shark cartilage extract prepared by extraction shark cartilage at 4-120°C for 2-4 hours, cooling the extract and separating supernatant from pellet by centrifugation. This supernatant (supernatant 1) is combined with the supernatant 2 obtained by the repeated extraction with water of the pellet remaining after supernatant 1 separation.

Dupont et al teach shark cartilage extract. See summary and claim 1. The reference teaches that methods of obtaining shark cartilage extracts are well known. Among other methods, known methods include aqueous extractions in water or salt solutions and elimination of unsolubilized material. See column 2, lines 30-45. Further, the patent describes preparation of shark cartilage extract by extraction by water, and separation of unsolubilized material by centrifugation. Many other aqueous solutions can be used in lieu of water. See col. 4, last two paragraphs. The composition of the supernatant is disclosed in the table, column 5. Several different

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fractions of supernatant can be further separated, as disclosed in columns 10,11. Pharmaceutical compositions comprising the shark cartilage extract were use for treatment of several disease conditions. See columns 13-18.

Claims 2,15 are in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need to be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, USPQ (CCPA 1976). Therefore, as Dupont et al teach shark cartilage extract, the reference anticipates the instantly claimed product. Since the Office does not have the facilities for examining and comparing applicants' extract with the extract disclosed in the prior art, the burden is on applicant to show novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.d. 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

In regard to claim 15 providing percentile content of the components in the extract, the reference either merely acknowledges the presence of a component (in regard to mucopolysaccharides; col. 5, line 60) or presents the content of the supernatant in a manner different from those used in the instant claims (in regard to protein, col. 5, line 41). Again, since the Office does not have the facilities for examining and comparing applicants' extract with the extract disclosed in the prior art, the burden is on applicant to show novel or unobvious difference between the

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claimed product and the product of the prior art. Further, it would be a matter of routine experimentation to select optimal concentration ranges of components of a cartilage composition.

7. Claim 8 is rejected under 35 U.S.C.103(a) as obvious over Halperin et al (US Patent 5,512,591) and Dupont et al (US Patent 5,618,925).

Halperin et al describes anti-angiogenesis agents and their use for treatment of angiogenesis-dependent disorders, such as cancers. The anti-angiogenesis agents of the reference can be used in anti-cancer cocktail comprising anti-angiogenesis agent and supplementary potentiating agents, such as antihypertensive agents and Ca antagonists (the latter also being anti-hypertensive agents). See col. 5, lines 1-5, 30-43. Thus, it would be *prima facie* obvious to use an anti-angiogenesis agent with an anti-hypertensive agent. Further, it would be obvious to use functional equivalents of anti-angiogenesis agents of Halperin. As such, one would be motivated to use other anti-angiogenesis agents with an anti-hypertensive. In particular, one would be motivated to use shark cartilage extract described in Dupont et al which is shown to have anti-angiogenic activity.

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Prior art made of record

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 3,371,012 teaches a shark cartilage extract prepared cartilage extraction with aqueous solution at 70°C for 3 hours and filtration of the extract through a "Celite" column. See col. 3, lines 20-31.

US 4,473,551 teaches a shark cartilage extract prepared by extraction of shark cartilage with water at temperature 0-50°C for 4-24 hours. The extraction procedure include repetitive extraction of the same portion of cartilage with new portions of water, to increase extraction of active components. See col. 2, lines 35-55.

US Patents 5985839, 6025118 and 6025334 are other patents of Dupont et al, all describing shark cartilage extracts and methods of their preparation.

Conclusion.

9. No claims are allowed

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 9, 2002

MICHAEL BORIN, PH.D.
PRIMARY EXAMINER

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.